Janssen COVID-19 Vaccine (Johnson & Johnson)

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- If the recipient has received 1 dose of a Janssen COVID-19 Vaccine, no additional primary-series doses are needed. A booster dose is recommended 2 months (8 weeks) after the primary dose; any FDA-authorized or approved COVID-19 vaccine may be given.
- If the recipient has received 1 dose of an mRNA vaccine, the same brand should be administered for the second dose of the primary series.
- In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine, (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. See footnote for further information on administering Janssen COVID-19 Vaccine to persons with a contraindication to mRNA COVID-19 vaccines. ‡
- A person is considered fully vaccinated ≥ 14 days after a single dose of Janssen COVID-19 Vaccine has been administered or after completing a 2-dose series of an mRNA vaccine. All persons who received a single dose Janssen COVID-19 Vaccine should get a booster dose of a COVID-19 vaccine at least 2 months (8 weeks) after receiving the primary dose. Those vaccinated with a 2-dose mRNA vaccine series should receive a 3rd dose if moderately to severely immunocompromised at least 28 days after completing a two-dose series. A booster dose (at least 6 months after completing a primary mRNA series or after an additional dose) is recommended for different age and risk groups. See CDC clinical considerations for more information (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html).
- Thrombocytopenia syndrome (TTS) and thrombocytopenia:
  - Inform women aged 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group after Janssen COVID-19 vaccination and about the availability of other authorized vaccines (i.e., mRNA vaccines).
  - Offer another FDA-authorized or approved vaccine (i.e., mRNA vaccine) to persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized or approved COVID-19 vaccine.

NOTE: Persons at risk or with a history of other thrombosis not associated with thrombocytopenia can receive an FDA-authorized or approved vaccine

- People with a history of Guillain-Barré Syndrome (GBS):
  - Can receive any FDA-authorized or approved COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, discuss with these patients the availability of mRNA COVID-19 vaccines that offer protection against COVID-19.

Booster doses:

- Administer a booster (2nd) dose at least 2 months (8 weeks) after completion of the Janssen COVID-19 Vaccine primary dose to:
  - All persons who received the Janssen COVID-19 Vaccine
  - Use of heterologous booster doses is allowed.
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Janssen COVID-19 Vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.*
- Defer vaccination with Janssen COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

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- **Screen for contraindications and precautions.**
  - Contraindications
    - Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
    - Immediate allergic reaction[†] of any severity or known (diagnosed) allergy to a component of the vaccine ((See the chart at the end of this document for a list of ingredients in COVID-19 vaccines)

Note: Persons who have a contraindication to Janssen COVID-19 Vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).[‡]

  - Precautions
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - History of an immediate allergic reaction[†] of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
      - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - People with a contraindication to an mRNA COVID-19 vaccine have a precaution to the Janssen COVID-19 Vaccine (see footnote).[±]
    - Moderate to severe acute illness

[#]Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

[*]When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines., They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

[†]For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

[‡]Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site[‡]
Female or male fewer than 130 lbs	22–25	⅝[§] –1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

[‡]Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

[§]Some experts recommend a 5/8-inch needle for men and women who weigh less than 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 18 years of age:
    - Needle gauge/length: 22-25 gauge, 1-inch
    - Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart on page 2.
  - Follow the manufacturer's guidance for storing/handling punctured vaccine vials.
  - Administer 0.5 mL Janssen COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the

administering clinic or healthcare professional. Give to the vaccine recipient.

- » Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

- Additional preparation and administration information is available on the manufacturer's website at www.janssencovid19vaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - » **30 minutes:** Persons with a:
      - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine
      - History of anaphylaxis due to any cause
    - » **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - » **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**

- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - » Serious AEs (irrespective of attribution to vaccination)
    - » Multisystem inflammatory syndrome (MIS) in adults or children
    - » Cases of COVID-19 that result in hospitalization or death
    - » Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - » Clinically important adverse events that occur after vaccination, even if they are not sure whether the vaccine caused the adverse event

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Kansas Local Health Departments effective 11/05/2021 until rescinded or until 11/04/2022.

Medical director (or other authorized practitioner)

Lee A. Norman MD / _____ / _____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

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Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

* None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients in vaccines and medications can be found in the package insert. CDC's vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as resources.